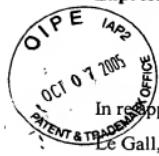


Express Mail No.: EV685780629US

Date Mailed: October 7, 2005



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Le Gall, et al.

Appl. No. 10/527,346

Filed: March 9, 2005

For: HUMAN CD3-SPECIFIC ANTIBODY  
WITH IMMUNOSUPPRESSIVE  
PROPERTIES

Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Atty. Docket: 03528.0146.PCUS00

Confirmation No.: 7228

#  
5

## Information Disclosure Statement

Mail Stop Amendment  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been

cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed:
  - a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
  - b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - c. Before the mailing date of a first Office Action on the merits;
  - d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

or;

- 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
  - a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or
  - c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
- 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of

Allowance, but on or before payment of the Issue Fee. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i), and

a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or

b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

4. Relevance of the non-English language document(s) is discussed in the present specification.

5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.

6. A concise explanation of the relevance of the non-English language document(s) appears below:

7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

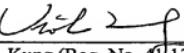
8. Copies of the documents were cited by or submitted to the Office in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 03528.0146.PCUS00.

Respectfully submitted,

Date: October 7, 2005

  
\_\_\_\_\_  
Viola T. Kung (Reg. No. 40,131)

**HOWREY SIMON ARNOLD & WHITE, LLP**  
2941 Fairview Park Drive  
Suites 200 & 300  
Falls Church, Virginia 22042  
Tel: (650) 463-8181  
Fax: (650) 463-8400



LIST OF REFERENCES CITED BY APPLICANT  
(Use several sheets if necessary)

PTO FORM 1449

|                                       |                               |
|---------------------------------------|-------------------------------|
| ATTY. DOCKET NO.<br>03528.0146.PCUS00 | APPLICATION NO.<br>10/527,346 |
| APPLICANT                             |                               |
| Le Gall, et al.                       |                               |
| FILING DATE<br>March 9, 2005          | GROUP                         |

## U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|-------------------|-----------------|------|------|-------|----------|----------------------------|
| 1.                |                 |      |      |       |          |                            |
| 2.                |                 |      |      |       |          |                            |
| 3.                |                 |      |      |       |          |                            |
| 4.                |                 |      |      |       |          |                            |

## FOREIGN PATENT DOCUMENTS

| *EXAMINER INITIAL | DOCUMENT NUMBER | DATE       | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|-------------------|-----------------|------------|---------|-------|----------|-------------|----|
|                   |                 |            |         |       |          | YES         | NO |
| 5.                | WO 99/57150     | 11/11/1999 | PCT     |       |          |             |    |
| 6.                | EP 0 952 218    | 10/27/1999 | EP      |       |          |             |    |

## OTHER REFERENCES

(Including Author, Title, Date, Pertinent Pages, Etc.)

|     |   |
|-----|---|
| 7.  | International Search Report   |
| 8.  | Bitter, et al., "Expression and Secretion Vectors for Yeast," <i>Methods Enzymol.</i> 153:516-544 (1987)  |
| 9.  | Bothmann and Pluckthun, "Selection for a periplasmic factor improving phage display and functional periplasmic expression," <i>Nat. Biotechnol.</i> 16:376-380 (1998)                               |
| 10. | Bradford, A Rapid and Sensitive Method for the Quantitation of the Microgram Quantities of Protein Utilizing the Principle of Protein-Dye Binding," <i>Anal. Biochem.</i> 72:248-254 (1976)         |
| 11. | Broglie, R., et al., "Light-Regulated Expression of a Pea Ribulose-1,5-Bisphosphate Carboxylase Small Subunit Gene in Transformed Plant Cells," <i>Science</i> 224:838-843 (1984)                   |
| 12. | Cochloulias, et al., "Treatment of Human B Cell Lymphoma Xenographs with a CD3 x CD19 Diabody and T Cells," <i>J. Immun.</i> 165:888-895 (2000)   |
| 13. | Colbère-Garapin, et al., "A New Dominant Hybrid Selective Marker for Higher Eukaryotic Cells," <i>J. Mol. Biol.</i> 150:1-4 (1981)  |
| 14. | Cole, M.S., et al., "Human IgG2 Variants of Chimeric Anti-DC3 Are Nonmitogenic to T Cells," <i>J. Immunol.</i> 159:3613-3621 (1997)   |
| 15. | Coruzzi, G., et al., "Tissue-specific and light-regulated expression of a pea nuclear gene encoding the small subunit of ribulose-1,5-bisphosphate carboxylase," <i>EMBO J.</i> 3:1671-1680 (1984)  |
| 16. | Engelhard, et al., "The insect tracheal system: A conduit for the systemic spread of <i>Autographa californica</i> M nuclear polyhedrosis virus," <i>Proc. Natl. Acad. Sci.</i> 91:3224-3227 (1994) |
| 17. | Hartman and Mulligan, "Two dominant-acting selectable markers for gene transfer studies in mammalian cells," <i>Proc. Natl. Acad. Sci.</i> 85:8047-8051   |
| 18. | Hobbs, S. or Murry, L.E. in McGraw Hill Yearbook of Science and Technology (1992) McGraw Hill, New York, N.Y.; pp. 189-196  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Z.S./  
DM\_US18257027.1

LIST OF REFERENCES CITED BY APPLICANT  
(Use several sheets if necessary)

PTO FORM 1449



|                                       |                               |
|---------------------------------------|-------------------------------|
| ATTY. DOCKET NO.<br>03528.0146.PCUS00 | APPLICATION NO.<br>10/527,346 |
| APPLICANT                             |                               |
| Le Gall, et al.                       |                               |
| FILING DATE<br>March 9, 2005          | GROUP                         |

|     |   |
|-----|---|
| 19. | Holck and Kleppe, "Cloning and sequencing of the gene for the DNA-binding 17K protein of <i>Escherichia coli</i> ," <i>Gene</i> 67:117-124 (1988)   |
| 20. | Horn, "High volumetric yields of functional dimeric miniantibodies in <i>Escherichia coli</i> , using an optimized expression vector and high-cell-density fermentation under non-limited growth conditions," <i>Appl. Microbiol. Biotechnol.</i> , 46:524-532 (1996)             |
| 21. | Kipriyanov, et al., "Two amino acid mutations in an anti-human CD3 single chain Fv antibody fragment that affect the yield on bacterial secretion but not the affinity," <i>Protein Engineer</i> , 10:445-453 (1997)  |
| 22. | Kipriyanov, et al., "Bispecific CD3 x CD19 Diabody For T Cell-Midiated Lysis of Malignant Human B Cells," <i>Int. J. Cancer</i> 77:763-772 (1998)   |
| 23. | Logan and Shenk, "Adenovirus tripartite leader sequence enhances translation of mRNAs late after infection," <i>Proc. Natl. Acad. Sci.</i> 81:3655-3659 (1984)  |
| 24. | Lowy, I. et al., "Isolation of Transforming DNA: Cloning the Hamster apt Gene," <i>Cell</i> 22:817-823 (1980)   |
| 25. | Marks, et al., "By-passing Immunization: Building High Affinity Human Antibodies by Chain Shuffling," <i>Biotechnology</i> 10:779-783 (1997)  |
| 26. | Maurer, et al., "Gene Regulation at the Right Operator ( $O_R$ ) of Bacteriophage $\lambda$ ," <i>J. Mol. Biol.</i> 139:147-161 (1980)  |
| 27. | Mersmann, et al., "Monitoring of scFv selected by phage display using detection of scFv - pIII fusion proteins in a microtiter scale assay," <i>J. Immunol.</i> 200:51-62 (1996)  |
| 28. | Mottram, P. L., et al., "New Anti-CD3 Agents For Transplantation Tolerance Induction," <i>Drugs of the Future</i> 23(10):1091-1098 (1998)   |
| 29. | Rhodes, C.A., et al., "Transformation of Maize by Electroporation of Embryos," <i>Methods Mol. Biol.</i> 55:121-131 (1995)  |
| 30. | Sambrook, et al., <i>Molecular Cloning, Cold Spring Harbor Laboratory Press</i> (1989)  |
| 31. | Scharf, et al., "Heat Stress Promoters and Transcription Factors," <i>Springer-Verlag Berlin Heidelberg</i> 125-162 (1994)  |
| 32. | Takamatsu, et al., "Expression of bacterial chloramphenicol acetyltransferase gene in tobacco plants mediated by TMV-RNA," <i>EMBO J.</i> 6(2):307-311 (1987)   |
| 33. | Thisted, et al. "Mechanism of post-segregational killing: Sok Antisense RNA interacts with Hok mRNA via its 5'-end single-stranded leader and competes with the 3'-end of Hok mRNA for binding to the mok translational initiation region," <i>EMBO J.</i> 13(8):1960-1968 (1994) |
| 34. | Wigler, et al., "Transfer of Purified Herpes Virus Thymidine Kinase Gene to Cultured Mouse Cells," <i>Cell</i> 11:223-232 (1977)  |
| 35. | Wigler, et al., "Transformation of mammalian cells with an amplifiable dominant-acting gene," <i>Proc. Natl. Acad. Sci.</i> 77(6):3567-3570 (1980)  |
| 36. | Winter, J., et al. "The Expression of Heat Shock Protein and Cognate Genes During Plant Development," <i>Results Probl. Cell Differ.</i> 17:85-105 (1991)   |
| 37. |   |
| 38. |   |
| 39. |   |

/Zachary Skelding/

09/11/2008

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.